

Appendix A of this guidance has been superseded by Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data Attachment 1. List of SUDS Known to be Reprocessed or Considered for Reprocessing.

List I. Critical Reprocessed Single-Use Devices Previously Exempt from Premarket Notification Requirements that Will Now Require 510(k)s with Validation Data (*to be submitted by July 30, 2004, unless otherwise noted*).

<u>21 CFR No.</u>	<u>Classification Name</u>	<u>Product Code for non-reprocessed device</u>	<u>Product Code for reprocessed device</u>	<u>Product Code Name for reprocessed device</u>
872.3240	Dental bur	Diamond Coated	NME	Dental diamond coated bur
872.4535	Dental diamond instrument	DZP	NLD	Dental diamond instrument
872.4730	Dental injection needle	DZM	NMW	Dental needle
874.4140	Ear, nose, and throat bur	Microdebrider	NLY	ENT high speed microdebrider
874.4140	Ear, nose, and throat bur	Diamond Coated	NLZ	ENT diamond coated bur
874.4420	Ear, nose, throat manual surgical ..	KAB, KBG, KCI	NLB	Laryngeal, Sinus, Tracheal trocar
876.1075*	Gastroenterology -urology biopsy instrument	FCL	NON	Non-Electric biopsy forceps
878.4200	Introduction/drainage catheter and accessories	GCB	NMT	Catheter needle
878.4800	Manual surgical instrument	MJG	NNA	Percutaneous biopsy device
878.4800	Manual surgical instrument	FHR	NMU	Gastro-Urology needle
878.4800	Manual surgical instrument for	DWO	NLK	Cardiovascular biopsy needle
878.4800	Manual surgical instrument for..... ..	GAA	NNC	Aspiration and injection needle
882.4190	Forming/cutting clip instrument	HBS	NMN	Forming/cutting clip instrument
884.1730	Laparoscopic insufflator,	HIF	NMI	Laparoscopic insufflator and accessories

884.4530	OB/GYN specialized manual instrument	HFB	NMG	Gynecological biopsy forceps
886.4350	Manual ophthalmic surgical instrument	HNN	NLA	Ophthalmic knife

* 510(k)s with validation data to be submitted by [insert date 15 months after date of publication in the **Federal Register**]